K092528 (pg 1/2)

BIOMET TRAUMA

MAY 21 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter:	Biomet Trauma 100 Interpace Parkway Parsippany, NJ 07054
Establishment Registration Number:	2242816
Contact:	Margaret F. Crowe Regulatory Affairs Project Manager Biomet Trauma 100 Interpace Parkway Parsippany, NJ 070654 Tel.: 973-299-9300, ext. 2260 Fax: 973-257-0232 E-mail: margaret.crowe@ebimed.com
Date Prepared:	May 21, 2010
Trade/Proprietary Name:	Biomet Forerunner™ Plating System
Common/Usual Name:	Plates/Screws
Classification Name:	Single/multiple metallic bone fixation appliances and accessories (21 CFR 888.3030)
Device Panel/Product Code:	Orthopedics HRS/HWC

Device Description:
The Biomet Forerunner™ Plating System is an internal fixation system consisting of various sized plates and screws. The plates and screws are fabricated from Ti-6Al-4V.

Indications for Use:
The indications for use for this system have been modified. The Biomet Forerunner™ Plating System is currently indicated for use in adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically

prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, metacarpals, metatarsals, humerus, ulna, radius, middle hand and middle foot bones.

This premarket notification expands the indications for use to the forefoot, and adds the following specific indications for midfoot/forefoot procedures:

1. Treatment of fractures and fracture-dislocations of the midfoot/forefoot
2. Malunions
3. Non-unions
4. Joint fusions/arthrodesis
5. Corrective osteotomies for deformities

These procedures in the midfoot/forefoot may be indicated as a result of trauma, deformity, osteoarthritis, and rheumatoid arthritis.

Summary of Technologies:
The technological characteristics of the Forerunner™ Plating System are the same as, or similar to, the predicate devices.

Substantial Equivalence:
The Forerunner™ Plating System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. Examples of predicate devices include:

- DARCO Locked Universal Plate – marketed by Wright Medical Technology, Inc. – cleared under premarket notification K061808,
- Charlotte Claw Compression Plate – marketed by Wright Medical Technology, Inc.- cleared under premarket notifications K080295 and K051908

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 21 2010

Biomet Trauma (aka EBI, LP)
% Ms. Margaret Crowe
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, NJ 07054

Re: K092528
Trade/Device Name: Biomet Forerunner Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 19, 2010
Received: May 20, 2010

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bucheres

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092852 (pg 1/1)

Device Name: Biomet Forerunner™ Plating System

The Biomet Forerunner™ Plating System is used for adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, metacarpals, metatarsals, humerus, ulna, radius, middle hand, and middle foot bones. This 510(k) expands the indications for use to the forefoot, and adds specific indications for midfoot/forefoot procedures:

1. Treatment of fractures and fracture-dislocations of the midfoot/forefoot
2. Malunions
3. Non-unions
4. Joint fusions/arthrodesis
5. Corrective osteotomies for deformities

These procedures in the midfoot/forefoot may be indicated as a result of trauma, deformity, osteoarthritis, and rheumatoid arthritis.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Temperature

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092852